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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/607,602	06/30/2000	Matthew Joseph Doyle	8141	8543

27752 7590 10/21/2002

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CINCINNATI, OH 45224

EXAMINER

DECLoux, AMY M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 10/21/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/607,602

Applicant(s)

DOYLE ET AL.

Examiner

Amy M. DeCloux

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 29 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2-4 and 7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-4 and 7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Applicant's amendment filed 7-29-02 (Paper No. 7) is acknowledged and has been entered, as has Applicant's declaration by inventor Singer, filed 7-29-02 (Paper No. 8).

Claims 2-4 and 7 are pending. Applicant cancelled claims 1, 5 and 6 in said amendment.

In view of Applicant's amendment filed 7-29-02 (Paper No. 7), the 112 second paragraph rejections have been withdrawn.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

MAINTAINED Claims 1-4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Pan et al (WO 97/16159).

MAINTAINED Claims 1-4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Singer et al (U.S. No. 5,364,616).

MAINTAINED Claims 1- 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsujita et al (JP 04089428A).

### ***Response to Arguments***

Applicant's arguments filed 7-29-02 have been fully considered but they are not persuasive.

Applicant traverses the rejection on the grounds that the present claims are directed to a new use of topical administration of a H2 antagonist that are novel and unobvious in view of the cited references.

Applicant reinforces this novelty by Applicant's declaration by inventor Singer, filed 7-29-02 (Paper No. 8) which states on page 4 that "the ability of H2 agonists to increase the natural barrier function of gingival tissues..... unexpectedly also represents an effective approach to preventing oral pathogens and their products from entering from entering into either the gingival tissues or the systemic circulation. Consequently topical application of H2 antagonists affords

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unanticipated benefits for preventing oral pathogens from promoting the systemic inflammatory mechanisms and complications that contribute to systemic diseases/disorders such as atherosclerosis, stroke, diabetes, and low birth weight infants.”

However, the examiner notes that because the process steps are not novel and thus the results of the process steps are inherent

Applicant argues that this inherency is immaterial if one of skill would not recognize the inherent result. Applicant further contends that claims drawn to a method for using either an old or obvious composition wherein the method has unobvious beneficial or useful effects have been found patentable even though the composition itself could not be patented. However Applicant's contention does not require that the method steps in Applicant's referenced method for using either an old or obvious composition, to have been taught in combination with said composition.

The examiner notes that in the instant case, the method steps taught by the prior art are the same method steps as those instantly recited. Preamble language in claims of patents directed to administration of anticancer drugs are expressions of purposes and intended results, and as such are nonlimiting, since language does not result in manipulative difference in steps of claims. The instant case does not present a situation in which the new use of a process should be considered limiting because it distinguishes process over prior art (Bristol Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001), previously 00-1304 (CAFC 4/20/01)).

Applicant contends that patentability of the instant claims centers on whether or not the claimed new use is obvious to one of skill in the art. However the examiner notes that newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent. See MPEP 2112-2112.02.

### ***Conclusion***

No Claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

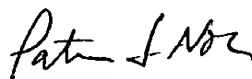
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.  
Patent Examiner,  
October 12, 2002

  
Patrick J. Nolan, Ph.D.  
Primary Patent Examiner,  
Group 1640